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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/872,623	06/02/2001	Thomas T. Andersen	010.00121 2288		
75	90 01/23/2003				
Ivor R. Elrifi, Esq.			EXAMI	EXAMINER	
Mintz Levin One Finacial Center			HUFF, SHEELA JITENDRA		
Boston, MA 02	2111		ART UNIT	PAPER NUMBER	
		·	1642	٠ .	
			DATE MAILED: 01/23/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application N .	Applicant(s)			
		09/872,623	ANDERSEN ET AL.			
		Examiner	Art Unit			
		Sheela J Huff	1642			
Period fo	The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1)🖂	Responsive to communication(s) filed on 26 November 2002.					
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>						
4)⊠	Claim(s) 1-22 is/are pending in the application.					
	4a) Of the above claim(s) <u>16-22</u> is/are withdrawn from consideration.					
	Claim(s) is/are allowed.					
6)⊠	☑ Claim(s) <u>1-8 and 13-15</u> is/are rejected.					
7)🖂	)⊠ Claim(s) <u>9-12</u> is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) 🗌 -	The drawing(s) filed on is/are: a)□ accep	ted or b)⊡ objected to by the Exan	niner.			
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).			
11) 🔲 -	The proposed drawing correction filed on	is: a) ☐ approved b) ☐ disapprov	ved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
<ul> <li>a)  The translation of the foreign language provisional application has been received.</li> <li>15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>						
Attachment(s)						
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal Pa	PTO-413) Paper No(s) atent Application (PTO-152)			

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#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of Group I, claims 1-15 in Paper No. 10 is acknowledged. The election of species has been withdrawn and all SEQ ID no. have been examined.

### **Priority**

After a careful review of 60/208614, the Examiner determined that the the complete subject matter of the currently pending claims cannot be found in the provisional application and therefore, the instant application is only entitled to 6/2/01 for its filing date.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Mesfin et al. Proc. Of the American Assn. For Cancer Research vol. 41 p. 375 (3/00), Abstract #2380.

a.

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This reference discloses the peptide EMTPVNPG.

Claims 1-3, 5 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Mesfin et al. Proc. Of the American Assn. For Cancer Research vol. 42 p. 778 (3/00), Abstract #4178.

This reference discloses peptide EMTPVNP (linear and cyclic form) and EMTOVNOG. This peptide is found in a composition (ie purification buffers).

Claims 1-3, 5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al Cancer Detection and Prevention vol. 24 (Supp. 1) 2000.

This reference discloses EMTPVNPG, QMTPVNPG, QMTPVNPGE, analogs and cyclized forms thereof and these are in a composition.

Claims 1-2, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Vakharia et al, Breast Cancer Research and Treatment vol. 63 p. 41 (2000).

This reference discloses EMTPVNPGV (p. 43) and its used in a composition (see assay description on page 42).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantley et al US 5532167, This reference discloses SEQ ID No. 36 which reads on a analog of SEQ Id no. 6 of the instant invention.

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Claims 1-3, 6-8 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizejewski US 5707963.

This reference discloses SEQ ID No. 4 and 5 which read on SEQ ID no. 2, 5 d and 10-11 of the instant invention. These peptide can be labeled and the labels include radioactive labels and the peptides are formed in compositions inclusind stabilization ingredients (see col. 3, lines 43 to col. 4, lines 21 and col. 5 lines 1-55).

Claims 1-4 and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Krystal et al US 6348567.

This reference discloses SEQ ID No. 5 which reads on an analog of SEQ ID No. 6 of the instant invention. The peptides can have D amino acids or be cyclic (col. 5 and 6 and col. 7, lines 12-15). The peptides are in compositions including a stabilization composition (col. 10, lines 12+).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizejewski US 5707963 or Krystal et al US 6348567 in view of applicant's admission on page 9, lines 20-25 of the specification.

The primary references have been discussed above.

The only difference between the instant invention and the reference is the use of mannitol or dodecy/maltoside are the stabilizer.

On page 9 of the specification, applicant discloses that these stablizers are known in the art.

Therefore, in view of applicant's admission, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use mannitol or dodecyl maltoside as stabilizers.

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Allowable Subject Matter

Claims 9-12 are objected to as being dependent upon a rejected base claim, but

would be allowable if rewritten in independent form including all of the limitations of the

base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Sheela J Huff whose telephone number is 703-305-

7866. The examiner can normally be reached on T,Th 6am-12pm and alternate

Mondays 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone

numbers for the organization where this application or proceeding is assigned are 703-

308-4242 for regular communications and 703-308-4242 for After Final

communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is 703-308-

1235.

Sheela J Huff

Primary Examiner

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